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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,625	12/21/2001	Sabine Stumvoll	25401-5	1495

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/027,625	STUMVOLL ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 09/20/2007 is acknowledged.

2. Claims 30-36 are pending and under consideration.

3. In view of the amendment filed on 09/20/2007, only the following rejections is maintained.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 30-31, 33-34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Duro et al. (Reference AD; IDS filed 07/01/2002).

Duro et al., teaches serologically (from serum) identifying an individual known to be weed pollen allergic (P. judaica pollen allergic) as Parietaria allergic comprising contacting serum from an individual known to be weed pollen allergic (P. judaica pollen allergic) with recombinant Par j 2, determining the presence of IgE binding to said recombinant Par j 2 and identifying the individual as Parietaria allergic if the contacted serum contains IgE binding to the

recombinant Par j 2. Duro et al. also teaches that the characterization of the recombinant antigen is a preliminary step for use of said protein therapeutically. The prior art teaches all of the method steps of the claimed invention and as such anticipates the claimed invention. The preamble adds no additional limitations to the claims since the same product was used in the same method steps for identifying allergens from patients.

The reference teachings anticipate the claimed invention.

Applicant's arguments filed on 09/20/2007 have been fully considered but are not found persuasive

Applicant's argue:

"Applicants submit that the methods defined by claims 31-36 are not anticipated by and are patentably distinguishable from the teachings of Duro et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 30, the invention is directed to a method for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic, comprising contacting serum from an individual known to be weed pollen allergic with a pure Par j 1 or Par j 2 allergen component, determining the presence of IgE binding to said pure Par j 1 or Par j 2 allergen component; and identifying the individual as *Parietaria* allergic if the contacted serum contains IgE binding to said pure allergen component.

Thus, the present methods are for accurately identifying a *Parietaria* allergic individual, particularly when the individual is known to be generally weed pollen allergic. Applicants have determined that *Parietaria* pollen extract binds IgE from individuals not exposed to *Parietaria* pollen, while the recited pure allergen component Par j 1 or Par j 2 does not bind to IgE from such individuals. However, Par j 2 does bind IgE from most allergic individuals who are primarily sensitized to *Parietaria* pollen, as does Par j 1. Thus, Applicants have developed the present methods for specific

identification of *Parietaria* allergic individuals from those known to be weed pollen allergic.

Applicants submit that Duro et al fail to teach a method for serologically identifying an individual known to be weed pollen allergic as *Parietaria* allergic. That is, the Duro et al publication is directed to a single allergen source, namely *Parietaria judaica* pollen, and does not mention other allergen sources or individuals known generally to be weed pollen allergic. While Duro et al seek to characterize one of at least 9 allergen components of this source, namely Par j 2, Duro et al are not concerned with any other allergy source. Further, by showing that 82% of the *Parietariajudaica* pollen sensitive patients' serum had IgE reacting with rParj 2, Duro et al merely show that Parj 2 is a major allergen (see page 297, right column, lines 18-21), and no other findings or conclusions are provided by Duro et al. Particularly, Duro et al do not teach or suggest that Par j 2, or any other pure allergen component, can be employed in order to serologically identify with improved accuracy a *Parietaria* allergic individual from a general weed pollen allergic individual, as recited in the present claims.

The Examiner previously stated "if the Par j 2 is a pure allergen component without cross-reactivity...then this information shows that 18% of the patients were not allergic to P. judaica." However, Duro et al provide no teaching or suggestion that Par j 2 is a pure allergen component with limited or no cross-reactivity. In response to the previously submitted Declaration Under 37 C.F.R. 1.132 of the co-inventor Dr. Paolo Colombo, confirming that the Duro et al paper does not disclose or suggest that the Par j 2 allergen has limited or no cross-reactivity with allergen components from other weed pollen allergen sources (paragraph 4) and thus does not teach or suggest using Par j 2, or any other purified allergen component, in methods for diagnosis of the actual sensitizing source from a variety of possible allergen sources (paragraph 4), the Examiner asserted that Applicants' own specification and claims show that Par j 2 is diagnostic of *Parietaria judaica* pollen allergy. However, the teachings of Applicants' specification and claims is not available as prior art to interpret what the Duro et al teachings would mean to one of ordinary skill in the art. As Duro et al do not teach or suggest that Par j 2 is a pure allergen component with limited or no cross-reactivity, and therefore suitable for use in identifying an individual to be weed pollen allergic as *Parietaria* allergic, Duro et al do not disclose a method for such identification.

Only in light of Applicants' specification can the Examiner conclude that the 18% of patients having serum which do not react with Par j 2 are inherently not allergic to *Parietaria judaica* and therefore must be allergic to another allergen from another allergen source while the 82% of patients having serum that reacts with Par j 2 are *Parietaria* allergic. Contrary to the Examiner's assertion that Duro et al need not "teach" that Par j 2 is non-cross-active, Applicants submit that Duro et al must provide this very teaching in order for one of ordinary skill in the art to employ Par j 2 in a method for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic.

As noted previously, the Examiner has asserted, without any support in the evidence of record, that it is well known that peptides have specific properties that are related to their length and sequence and that it is highly unpredictable that two peptides that lack 100% length and sequence identity will have the same properties. The Examiner concludes from these assertions that the properties of a given protein or peptide are novel and specific to that protein or peptide unless evidence is presented to the contrary. The Examiner's statements are not only unsupported on the record, they are contrary to the well known knowledge in the art of the cross-reactivity of pollens. In this regard, the Examiner's attention is directed to Aalberse et al, *Allergy,* 56:478-490 (2001) which discusses the cross-reactivity of IgE antibodies and particularly states "Homologous proteins from phylogenetically related grasses tend to be cross-reactive" (page 478, left column, lines 11-13), and Weber, *J. Allergy Clin. Immunol.,* 112 (2):229-239 (2003) which discusses in detail the cross-reactivity of pollens. Accordingly, Applicants have established, contrary to the Examiner's unsupported assertions, that weed pollens are well known to be cross-reactive. Thus, the failure of Duro et al to teach that Par j 2 is non-cross-reactive demonstrates that Duro et al do not teach the presently claimed methods for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic.

Duro et al disclose the cloning and characterization of the allergen Parj 2.0101, and generally mention that in a diagnostic/therapeutic approach, a preliminary step is to purify and characterize each major allergen. This is only a general statement relating to all allergens and all diagnostic and therapeutic strategies. Applicants find no teaching or suggestion regarding any specific diagnostic method or approach. Particularly, Applicants find no teaching or suggestion by Duro et al regarding a method for accurately identifying a *Parietaria* allergic individual.

Anticipation under 35 U.S.C. § 102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference. *In re Robertson,* 169 F.3d 743,745, 49 U.S.P.Q. 2d 1949, 1950 (Fed. Cir. 1999). In view of the failure of Duro et al to teach a method for serologically identifying an individual known to be weed pollen allergic as *Parietaria* allergic, particularly by use of a pure Par j 1 or Par j 2 allergen component having limited or no cross-reactivity, Duro et al do not anticipate the methods of claims 30-36. Accordingly, the rejection under 35 U.S.C. § 102 has been overcome. Reconsideration is respectfully requested."

It is the Examiner's position that Duro et al need not provide teaching or suggestion that Par j 2 is a pure allergen component with limited or no cross-reactivity. The Examiner is not relying upon the teaching in the specification for this assertion. The teaching in the specification is relied upon to only show the inherency of the method. Applicants acknowledge on page 7 of

the response filed on 09/20/2007 and the Examiner agrees that Par j 2 was known in the art to be a major allergen at the time of invention. Whether or not individuals in the prior art were knowingly being serologically identified as Parietaria allergic is not necessary as the method is inherently identifying them. The specification's disclosure is used as evidence of the inherency of the method. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art." It is not necessary that those of ordinary skill in the art at the time of invention knew that Par j 2 had limited or no cross-reactivity. Par j 2 inherently has limited or no cross-reactivity, so the method inherently identified Parietaria allergic individuals.

It remains the Examiner's position that peptides have specific properties that are related to their length and sequence and that it is highly unpredictable that two peptides that lack 100% length and sequence identity will have the same properties. Applicant's provide Aalberse et al. and Weber et al. to show that weed pollens are well known to be cross-reactive. However, Aalberse et al. and Weber et al. also support the Examiner's position that cross reactivity cannot be assumed to be present between any two allergens that are not 100% identical. In particular, Aalberse et al teaches that it is "tempting" to try to extract rules for allergen cross-reactivity and that it is "not as clear cut as one might wish." Aalberse et al. also teaches that complete cross-reactivity between allergens cannot be proven (In particular, 'Can cross-reactivity be predicted'

section on pages 486-487). The reference further teaches that homology and protein folding plays a role in cross-reactivity, but that there are more factors to consider (In particular, page 487). Determining that two allergens will or will not cross-react is not straight-forward and may actually be impossible to determine. Therefore, one would not assume that Par j 2 or Par j 1 would have cross-reactivity with other weed pollen allergens unless there was structural similarity between those allergens and other known weed pollen allergens. Structural similarity is the best way to predict cross-reactivity, but even then it's not reliable. Further, Weber et al. teaches that taxonomy reflects cross-reactivity. In the abstract Weber et al. teaches that panallergens are generally minor allergens that don't react with a majority of allergic sera, (unlike Par j 2 which reacts with over 80% of P. judaica allergic sera) (In particular, abstract, whole document).

6. The following rejection is necessitated by the amendment filed on 09/20/2007.

7. Claims 30-32 and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Costa et al. (PTO-892, Reference U).

Costa et al. teaches serologically (from serum) identifying an individual known to be weed pollen allergic (P. judaica pollen allergic) as Parietaria allergic comprising contacting serum from an individual known to be weed pollen allergic (P. judaica pollen allergic) with recombinant Par j 1, determining the presence of IgE binding to said recombinant Par j 1 and

identifying the individual as Parietaria allergic if the contacted serum contains IgE binding to the recombinant Par j 1. Costa et al. also teaches using Par j 1 T and B cell epitopes in immunotherapy (allergy treatment involving peptide derived from Parietaria species). The prior art teaches all of the method steps of the claimed invention and as such anticipates the claimed invention. The preamble adds no additional limitations to the claims since the same product was used in the same method steps for identifying allergens from patients.

The reference teachings anticipate the claimed invention.

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 24, 2007

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

Maher M. Haddad

MAHER M. HADDAD
PRIMARY EXAMINER